Lower Standards for RU-486? [1]

RU-486
FDA has acknowledged the **deaths of eight women associated with the drug, nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection.**[2] These and other cases have added up to a total of **950 adverse event reports** (AERs) as of March 31, 2006. These reports are based on the FDA's Adverse Event Reporting System, a voluntary system, with inherent underreporting.

Compare the adverse events associated with RU-486 with those of other drugs:

NeutroSpec
December 19, 2005 – Palatin Technologies voluntarily suspended sales and marketing of NeutroSpec. No definitive determination was made regarding the relationship between NeutroSpec and reported adverse events.

Tysabri
February 28, 2005 – Biogen voluntarily suspended marketing of the drug as well as its use in clinical trials until more detailed information could be gathered on one death and one other adverse event.

Palladone
July 13, 2005 – Purdue Pharma agreed to voluntarily suspend sales and marketing of Palladone in the US. "To date, FDA is not aware of any patients who had life-threatening side effects from drinking alcohol while taking Palladone."

Cylert
May 2005 – Abbott chose to stop sales and market on Cylert. "FDA was aware of 13 reports of liver failure resulting in liver transplant or death..." "...the reporting reate for liver failure with pemoline is 10 to 25 times greater than the background rate of liver failure in the general population." NOTE: RU-486 is 10 to 14 times more lethal to the mother than surgical abortion during the first 49 weeks of gestation when RU-486 is used in chemical abortions.

Bextra
April 7, 2005 – Pfizer voluntarily withdraws Bextra from the U.S. market. FDA had concluded that the overall risk versus benefit profile of Bextra was unfavorable. "The reporting rate to FDA's spontaneous reporting system for these serious skin reactions was significantly greater for Bextra than other COX-2 selective agents."

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[1] Data extracted from a letter from David W. Boyer, Assistant Commissioner for Legislation, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 16, 2006) (on file with Subcommittee).
[2] Letter from David W. Boyer, Assistant Commissioner for Legislation, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 2, 2006) (on file with Subcommittee).

Vioxx
September 30, 2004 – Merck voluntarily withdraws Vioxx from US market. FDA was in the process of reviewing the cardiovascular events to determine whether labeling changes were warranted when Merck decided to withdraw it.

Orlaam
August 23, 2003 – Roxane stated that it was discontinuing the sale and distribution of the product after current inventory was depleted following reports of severe cardiac-related events among opiate-addicted patients.

Baycol
August 8, 2001 – Bayer Pharmaceuticals voluntarily withdrew the product after FDA received reports of 31 deaths associated with the drug.

Raplon
March 27, 2001 – Organon announced it was voluntarily withdrawing the drug after receiving reports of five deaths occurring during the administration of the drug.

Lotronex
November 28, 2000 – Glaxo Wellcome informed FDA it was voluntarily withdrawing Lotronex, after FDA received a total of 70 cases of serious adverse events, of which 34 required hospitalization without surgery, 10 resulted in surgical procedures, and three resulted in death.

Rezulin
March 21, 2000 – Manufacturer agreed to withdraw Rezulin after the drug showed it was more toxic to the liver than two other drugs.

Trovan
June 1999 – FDA issued a public health advisory when it received over 100 reports of patients who were ill with symptoms of liver toxicity. FDA was aware of 14 cases in patients whose livers actually failed.

Duract
June 22, 1998 – Wyeth-Ayerst announced it was withdrawing the analgesic, Duract, following reports of rare severe liver failure in patients in whom the drug was used for extended periods of time which was not in accordance with labeling instructions.

Tegison
March 1998 – Hoffman-La Roche voluntarily discontinued marketing Tegison because the product posed a greater risk of birth defects than a replacement product.